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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,303	11/27/2001	Robert C. Beck	2446	1374

7590 02/12/2004  
Beck & Tysver, P.L.L.C.  
2900 Thomas Avenue S., Suite 100  
Minneapolis, MN 55416

EXAMINER

DESANTO, MATTHEW F

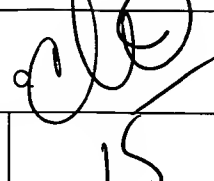
ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 02/12/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/995,303	Applicant(s) BECK, ROBERT C. 	
	Examiner Matthew F DeSanto	Art Unit 3763	15

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7-9, 18-24 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-9, 18-24 and 27-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are approved by the examiner, but must be approved by the draftsman, prior to issue.

### ***Specification***

2. The objection is withdrawn due to arguments and amendments.

### ***Claim Objections***

3. Claims 29, 30, 31 are objected to because of the following informalities: The examiner wants to point out that the claim numbers for 29, 30 and 31 vary in paper number 14D and 10C.
4. The examiner thinks that the claim numbers are misnumbered in paper number 14. The examiner is interpreting claim 30 to be claim 29, and claim 31 to be claim 30, and the dependence to change as well. Claim 29 will be dependent on 7 and claim 30 will be dependent on claim 28. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
6. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 9 is rejected because the claim is unclear because of the term "expands." The examiner does not understand what "expands"? It seems to the examiner that the fluid injected "expands", and this makes the claim unclear.

8. The 112 Rejection made in the prior office action is withdrawn because of arguments and amendments.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 7-9, 18-24, 27, 28, 29, 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Nash et al. (USPN 6,524,323).

Nash et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said

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therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figures 10, 11, 16, 17; Column 26, line 52 – Column 29, line 40 and entire reference)

As to claim 18, wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath.

As to claim 9, wherein said fluid is injection at a first injection pressure above the blood pressure in the vessel and expands to second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen.

As to claim 27, wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection.

3. Claims 7-9, and 18-24, 27, 28, 29, 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Levin et al. (USPN 6,592,567).

Levin et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said

therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figures 3, 7 and entire reference)

As to claim 18, wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath. (Figures 3, 7 and entire reference)

As to claim 9, wherein said fluid is injection at a first injection pressure above the blood pressure in the vessel and expands to second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen. (Figures 3, 7 and entire reference)

As to claim 27, wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection. (Figures 3, 7 and entire reference)

4. Claims 7-9, 18-24, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (USPN 5100425).

Fischell et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located

distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen.

Fischell et al. also discloses an infusion means and a discharge means.  
(Column 5, line 62- Column 6, line 15)

5. Claims 7-9, 18-24, and 27-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Zadno-Azizi et al. (USPN 6,605,074).

Zadno-Azizi et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figure 24A, and entire reference)

Zadno-Azizi et al. also discloses an infusion means and a discharge means.  
(Figure 24A, and entire reference)

### ***Response to Arguments***

6. Applicant's arguments and amendments filed 11/24/03 have been fully considered and Carbo et al. and Neracher have been withdrawn.

7. Applicant's arguments with respect to claims 7-9, 18-24, 27-30 has been considered but are moot in view of the new ground(s) of rejection.

8. With regards to Fischell et al. the applicant argues language that is not in the claim. The Examiner does not understand the argument, since the limitation the applicant is arguing is not in the claim and therefore the limitation is given no patentable weight.

9. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.



Matthew DeSanto  
Art Unit 3763  
February 3, 2004



MICHAEL J. HAYES  
PRIMARY EXAMINER